## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation	) ) )
Plaintiff,	)
V.	) Civil Action No. 04-12457 PBS
Arthrex, Inc.	)
a Delaware Corporation	)
Defendant.	) ) _ )

## <u>DEFENDANTS' RESPONSES TO DEPUY MITEK'S STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT AND NO INEQUITABLE CONDUCT</u>

Pursuant to Rule 56.1 of the Local Rules, District of Massachusetts, Defendants

Arthrex, Inc. ("Arthrex") and Pearsalls, Ltd. ("Pearsalls") (together, "defendants") hereby submit
their Responses to DePuy Mitek's Statement of Undisputed Material Facts in Support of its

Motion for Summary Judgment of Infringement and No Inequitable Conduct ("Defendants'
Responsive Facts").

Mitek Fact #1: Undisputed.

Mitek Fact #2: Undisputed.

Mitek Fact #3: Undisputed.

Mitek Fact #4: Undisputed.

**Mitek Fact #5:** Undisputed.

Mitek Fact #6: Disputed. This passage is taken out of context and designed to mislead the Court into believing there is support for DePuy Mitek's proposed construction of the "basic and novel characteristics of the claimed invention." However, as originally filed, the first suture claim required only that the sterilized suture be comprised of two dissimilar yarns in direct intertwining contact. The specific materials were not part of the claim and it did not include the "consisting essentially of" limitation. Later during prosecution, Ethicon made two amendments to the claims. First, it abandoned the broad claims that required only that that braid be made of two dissimilar materials. The allowed claims were limited to so that the dissimilar materials had to be from the group of specifically-named materials and the word "comprising" was changed to "consisting essentially of." The first set of yarns are from a group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE. The second set of yarns were from the group consisting of PET, nylon and aramid.

The specification of the '446 patent identifies the basic and novel characteristics of the claimed invention (the specifically identified materials) as being a suture having two dissimilar yarns (of the materials claimed) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification and is confirmed by the attorney who prosecuted the application for Ethicon and is consistent with Dr. Steckel's description of his work. *See* Substitute Defendants' Arthrex, Inc.'s and Pearsalls, Ltd.'s Concise Statement of Material Facts in Support of their Motion for Summary Judgment ("Defendants' Facts") at ¶¶ 39, 44, 45, 56 (and exhibits thereto).

**Mitek Fact #7:** Disputed. This passage is taken out of context and designed to mislead the Court. The specification also suggests that while a braid made entirely of "highly lubricious polymers" can be used to make a highly pliable braid, such a braid "will be relatively

weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments." This theme that lubricious polymers are too weak for suture usage is repeated when the specification explains that a "volume fraction of lubricating yarns . . . above 80% may adversely affect the overall strength of the braid." The specification then explains that the proposed solution is to have a suture comprised of a heterogeneous braid made of two different fiber forming materials which exhibits "improved pliability and handling properties . . . without appreciably sacrificing" [the suture's] physical properties," namely its "physical strength and knot security." This proposed solution is repeated throughout the specification. The '446 patent specifically refers to "pliability" in connection with "resistance to bending," and "bending rigidity," which are the inverse of pliability. A handling property specifically identified in the '446 patent is "knot tie down." The '446 patent relies on what is called the "rule of mixtures" to attempt to demonstrate that this combination is an improvement in the art. The point made by the inventors is that gains in pliability and handleability by using the combination of highly pliable and lubricious, but relatively weak, materials with a stronger material outweighs the loss of suture strength. See Defendants' Facts at ¶¶ 25-30 (and exhibits thereto).

The specification of the '446 patent identifies the basic and novel characteristics of the claimed invention as being a suture having two dissimilar yarns (of the materials claimed) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification and is confirmed by the attorney who prosecuted the application for Ethicon and is consistent with Dr. Steckel's description of his work. *See* Defendants' Facts at ¶ 56 (and exhibits thereto).

Mitek Fact #8: Disputed. Pearsalls manufactures only the braid later processed by others to make a TigerWire suture. See Opp.Ex. 6<sup>1</sup> at 32.

> Mitek Fact #9: Undisputed.

> Mitek Fact #10: Undisputed.

Mitek Fact #11: Undisputed.

**Mitek Fact #12:** Disputed. FiberWire does not contain PE. Rather is contains UHMWPE, a substance that is not included within the meaning of "PE," as that term is described and claimed in the '446 patent. See Opp.Ex. 6 at 10-18; Opp.Ex. 14; Opp.Ex. 15; Opp.Ex. 11.

Mitek Fact #13: Undisputed.

Mitek Fact #14: Undisputed.

Mitek Fact #15: Undisputed.

Mitek Fact #16: Disputed. FiberWire does not contain PE. Rather is contains UHMWPE, a substance that is not included within the meaning of "PE," as that term is described and claimed in the '446 patent. See Opp.Ex. 6 at 10-18; Opp.Ex. 14; Opp.Ex. 15; Opp.Ex. 11.

Mitek Fact #17: Undisputed.

Mitek Fact #18: Disputed. This quote is taken out of context. FiberWire does not contain a yarn from "the first set." See Opp.Ex. 6 at 10-18; Opp.Ex. 14; Opp.Ex. 15; Opp.Ex. 11. *See also* Response to Mitek Fact #12.

Mitek Fact #19: Undisputed.

Mitek Fact #20: Disputed. FiberWire and TigerWire do not contain PE. Rather, they contain UHMWPE, substance that is not included within the meaning of "PE," as that term is described and claimed in the '446 patent.

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<sup>&</sup>quot;Opp.Ex." refers to exhibits attached to Defendants Opposition to DePuy Mitek's Motion for Summary Judgment of Infringement and No Inequitable Conduct. ("Defendants' Opp.").

In addition, this assertion is out of context and designed to mislead the Court into believing that there is support for DePuy Mitek's proposed claim construction, and that the addition of coating in FiberWire and TigerWire does not materially affect the basic and novel characteristics of the claimed invention. The specification of the '446 patent identifies the basic and novel characteristics of the claimed invention as being a suture having two dissimilar yarns (of the materials claimed) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification and is confirmed by the attorney who prosecuted the application for Ethicon and is consistent with Dr. Steckel's description of his work. *See* Defendants' Facts at ¶¶ 39, 44, 45, 56 (and exhibits thereto).

Multiple patents, including patents owned by Ethicon and its expert, and publications (including from Ethicon) indicate that coating affects handleability characteristics of a suture, including knot tie-down. This was also asserted by Ethicon and DePuy Mitek when they developed suture products and was confirmed by several Ethicon and DePuy Mitek witnesses. The '446 patent also states that coating improves the handling characteristics of the suture, including knot tie-down. FiberWire contains a coating to improve handling characteristics, including suture slide, knot tying and ease of passing suture through tissue. Coating also improves the pliability and knot strength and knot tying of FiberWire through its impact on the various fibers of the FiberWire yarn. *See* Opp.Ex. 6 at 10-18; Opp.Ex. 14; Opp.Ex. 15; Defendants' Facts at ¶ 56-58 (and exhibits thereto).

Moreover, one of the purposes of PET in FiberWire and TigerWire is to improve the knot tying ability of the suture braid and this is one of the undisputed and long-known reasons for coating a suture. Accordingly, even under DePuy Mitek's view of the basic and novel

characteristics of the claimed invention, coating has a material affect. See Opp.Ex. 13 at ¶ 15; see also Response to Mitek Fact #6.

Mitek Fact #21: Disputed. FiberWire does not contain PE. It contains UHMWPE, a substance that is not included within the meaning of "PE," as that term is described and claimed in the '446 patent. See Opp.Ex. 6 at 10-18; Opp.Ex. 14; Opp.Ex. 15; Opp.Ex. 11.

Mitek Fact #22: Disputed. This statement is taken out of context and is designed to mislead the Court. The claim interpretation issue is the meaning of "PE," as it is used in the '446 patent, to one of ordinary skill in the art in 1992 (when the patent application was filed). The answer to that dispositive question focuses primarily on the intrinsic evidence, the claims, specification and prosecution history of the '446 patents. Marketing documents written a decade later and which are completely divorced from the '446 patent are of no value and do nothing to aid the Court in deciding the real issues in the case. FiberWire does not contain "PE," as that term is described and claimed in the '446 patent. See Opp.Ex. 6 at 10-18; Opp.Ex. 14; Opp.Ex. 15; Opp.Ex. 11.

Mitek Fact #23: Undisputed.

Mitek Fact #24: Undisputed.

Mitek Fact #25: Undisputed.

Mitek Fact #26: Undisputed.

Mitek Fact #27: Undisputed.

Mitek Fact #28: Disputed. This quote is taken out of context and is designed to mislead the Court. Mr. Grafton explained that UHUMWPE has very high tensile strength, in fact, much stronger than any other materials used for suture. Opp.Ex. 10 at 45:10-46:8. In addition, Mr. Grafton made it clear that his understanding of "knot strength" has nothing to do with "knot security." Mr. Grafton testified that "knot strength" is determined by tying a knot in a suture and testing it on a tensile testing machine. Opp.Ex. 10 at 25:4-15. Mr. Grafton also testified that the test he conducted with Drs. Burkhart and Chen were "knot security tests" and not "knot strength tests." Opp.Ex. 10 at 51:22-52:2. Mr. Grafton also made it clear that the term "knot slippage" means the same thing to him as does "knot security." Opp.Ex. 10 at 53:12-19.

Mitek Fact #29: Undisputed.

Mitek Fact #30: Undisputed.

Mitek Fact #31: Undisputed.

Mitek Fact #32: Disputed. This statement is out of context and designed to mislead the Court. The passage also states that coating on FiberWire acts to improve suture sliding, knot tying and ease of passage through tissue. See Defendants' Facts at ¶ 58 (and exhibits thereto). Multiple patents, including patents owned by Ethicon and its expert, and publications (including from Ethicon) indicate that coating affects handleability characteristics of a suture, including knot tie-down. This was also asserted by Ethicon and DePuy Mitek when they developed suture products and was confirmed by several Ethicon and DePuy Mitek witnesses. The '446 patent also states that coating improves the handling characteristics of the suture, including knot tie-down. FiberWire contains a coating to improve handling characteristics, including suture slide, knot tying and ease of passing suture through tissue. Coating also improves the pliability and knot strength of FiberWire. See Defendants' Facts at ¶¶ 57, 58 (and exhibits thereto). Test data also confirms that coating affects both knot tie-down and the knot strength of FiberWire. See Opp.Ex. 6 at 24-25, 28-29.

Mitek Fact #33: Disputed. See Response to Mitek Fact #20. In addition, Dr. Brookstein's statements are disputed by Dr. Mukherjee. Dr. Mukherjee stated that the basic and novel characteristics described in the '446 patent are "a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without

significantly sacrificing its physical properties." *See* Opp.Ex. 6 at 18-21. Dr. Mukherjee also stated that "the coating added to Arthrex's FiberWire suture materially affects the pliability, handleability and physical properties of FiberWire." *See* Opp.Ex. 6 at 22-29.

**Mitek Fact #34:** Disputed. See Responses to Mitek Fact #20 and 33.

Mitek Fact #35: Undisputed.

Mitek Fact #36: Undisputed.

Mitek Fact #37: Disputed. See Responses to Mitek Fact #20 and 33.

**Mitek Fact #38:** Disputed. See Responses to Mitek Fact #20 and 33.

Mitek Fact #39: Undisputed.

Mitek Fact #40: Disputed. Dr. Mukherjee stated that the basic and novel characteristics described in the '446 patent are "a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties." Opp.Ex. 6 at 18-21. Dr. Mukherjee also stated that the nylon added to TigerWire suture materially affects its pliability. He stated that nylon 6,6 fibers used in TigerWire are generally more stiff (i.e., less pliable) than fibers made of PET, as used in FiberWire and TigerWire. Dr. Mukherjee also stated that Arthrex has received customer feedback that TigerWire is more stiff than FiberWire. Dr. Mukherjee confirmed this himself. He stated that he held a sample of both commercial FiberWire and TigerWire and the TigerWire felt stiffer and more course than the same sized FiberWire. He also conducted a drape test on the two samples and found that the FiberWire conformed to the shape of his finger to a much greater degree than the TigerWire, indicating that the addition of the nylon appears to make TigerWire stiffer and less pliable. Dr. Mukherjee also stated that the coarse feel of TigerWire, due to the nylon, indicated that the addition of the nylon would adversely affected knot tie-down. Opp.Ex. 6 at 30-31. See also Response to Mitek Fact #6.

**Mitek Fact #41:** Disputed. This assertion is out of context and designed to mislead the Court into believing that nylon does not affect the basic and novel aspects of the invention. *See also* Response to Mitek Fact #40.

**Mitek Fact #42:** Disputed. This assertion is out of context and designed to mislead the Court into believing that nylon does not affect the basic and novel aspects of the invention. *See also* Response to Mitek Fact #40.

**Mitek Fact #43:** Disputed. This assertion is out of context and designed to mislead the Court into believing that nylon does not affect the basic and novel aspects of the invention. *See also* Response to Mitek Fact #40.

**Mitek Fact #44:** Disputed. This assertion is out of context and designed to mislead the Court into believing that nylon does not affect the basic and novel aspects of the invention. *See also* Response to Mitek Fact #40.

**Mitek Fact #45:** Disputed. This quote is out of context and designed to mislead the Court into believing that nylon does not affect the basic and novel aspects of the invention. *See also* Response to Mitek Fact #40.

Mitek Fact #46: Undisputed.

Mitek Fact #47: Undisputed.

**Mitek Fact #48:** Disputed. This statement is incoherent.

Mitek Fact #49: Undisputed.

Mitek Fact #50: Undisputed.

Mitek Fact #51: Undisputed.

Mitek Fact #52: Undisputed.

Mitek Fact #53: Undisputed.

Mitek Fact #54: Undisputed.

Mitek Fact #55: Undisputed.

Mitek Fact #56: Undisputed.

Mitek Fact #57: Undisputed.

Mitek Fact #58: Undisputed.

Mitek Fact #59: Undisputed.

Mitek Fact #60: Undisputed.

Mitek Fact #61: Undisputed.

Mitek Fact #62: Undisputed.

Mitek fact #63: Undisputed.

Mitek Fact #64: Undisputed.

**Mitek fact #65:** Disputed. This statement is misleading and is designed to make the Court believe that a decision by the Patent Office to issue a restriction requirement because two inventions within the same application are "patentably distinct," is somehow related to a prior art rejection. There is absolutely no such relationship. As Mr. Witherspoon stated:

> all this discussion is in the context of making a restriction requirement. And words like patentably distinct and so on mean that you are entitled to those claims in another patent, at least you're entitled to prosecute them in another patent. We should keep in mind that this is not a discussion of obviousness in the sense of 103, however. This is an implementation of the Commissioner's instructions about how the Commissioner wants to take advantage and implement the authorization he gets in 121 about requiring restrictions. And you see the several citations, in fact, to the MPEP.

Opp.Ex. 20 at 155:3-18.

**Mitek Fact #66:** Disputed. This statement is misleading and is designed to make the Court believe that a decision by the Patent Office to issue a restriction requirement because two inventions within the same application "have acquired a separate status in the art because of their divergent subject matter," is somehow related to a prior art rejection. There is absolutely no such relationship. As Mr. Witherspoon stated:

> all this discussion is in the context of making a restriction requirement. And words like patentably distinct and so on mean that you are entitled to those claims in another patent, at least you're entitled to prosecute them in another patent. We should keep in mind that this is not a discussion of obviousness in the sense of 103, however. This is an implementation of the Commissioner's instructions about how the Commissioner wants to take advantage and implement the authorization he gets in 121 about requiring restrictions. And you see the several citations, in fact, to the MPEP.

Opp.Ex. 20 at 155:3-18.

**Mitek Fact #67:** Undisputed.

**Mitck Fact #68:** Disputed. See Responses to Mitck Fact #65 and 66.

Mitek Fact #69: Disputed. The first Office Action rejected the suture claims "under 35 U.S.C. § 103 as being unpatentable over Burgess (U.K. Patent Application No. 2,218,312A)." Opp.Ex. 2.

Mitek Fact #70: Disputed. The Burgess application discloses a fishing line with a heterogeneous braid of high tensile polythene (UHMWPE) and polyester and/or nylon. Opp.Ex. 1.

Mitek Fact #71: Undisputed.

Mitek Fact #72: Undisputed.

**Mitek Fact #73:** Disputed. This assertion is out of context and incomplete. Ethicon argued the Burgess braid would make a poor suture and would have poor knot strength and security. In particular, the combination would be poor because it contained UHMWPE, a product with "minimal stretchability" and which "suffers from poor elongation." Ethicon concluded by stating that "[e]ven if one were to look to the fishing line art, one would inevitably design an unacceptable suture." [Emphasis added.] In other words, Ethicon told the patent

examiner, and be extension the public, that the combination disclosed in Burgess – UHMWPE and polyester or nylon – would *not* make an acceptable suture. And the reason that the combination would be unacceptable was because it contained UHMWPE. See Defendants' Facts at  $\P$ ¶ 42, 43 (and exhibits thereto).

Mitek Fact #74: Disputed. This assertion is out of context and incomplete. See Response to Mitek Fact #73.

**Mitek Fact #75:** Disputed. The Burgess application does not disclose the properties discussed by Mr. Goodwin as properties for fishing line. See Opp.Ex. 1.

Mitek Fact #76: Disputed. This assertion is out of context and incomplete. See Response to Mitek Fact #73. In addition, the requirements for fishing line and suture are similar, as stated by the examiner in the Office Action rejecting the claims based on Burgess and confirmed by Dr. Mukherjee. Opp.Ex. 2; Fact.Ex. 2 at 17-18.

**Mitek Fact #77:** Disputed. *See* Response to Mitek Fact #76.

**Mitek Fact #78:** Disputed. *See* Response to Mitek Fact #76.

**Mitek Fact #79:** Disputed. *See* Response to Mitek Fact #76.

**Mitek Fact #80:** Disputed. *See* Response to Mitek Fact #76.

**Mitek Fact #81:** Disputed. *See* Response to Mitek Fact #76.

**Mitek Fact #82:** Disputed. *See* Response to Mitek Fact #76.

Mitek Fact #83: Undisputed.

Mitek Fact #84: Undisputed.

Mitek Fact #85: Undisputed.

Mitek Fact #86: Disputed. In the Response dated December 2, 1992, Mr. Goodwin stated "applicant acknowledge with gratitude the withdrawal of the rejection of claims 21-24 under 35 U.S.C. § 103 as being unpatentable over Burgess, expressed in the previous Office

Action dated July 8, 1992. (Paper No. 3). It is presumed that Applicants' response to this rejection in their Amendment dated August 6, 1992, spelling out the distinctions between Burgess and the claimed invention, clearly convinced the Examiner that the claimed surgical suture is patentable over this art." Opp.Ex. 27 at 7.

Mitek Fact #87: Undisputed.

**Mitek Fact #88:** Disputed. This statement is misleading since the rejection had nothing to do with the absorbable/non-absorbable issue. When the absorbable/non-absorbable issue was relevant, the next Amendment, Mr. Woodrow chose to paraphrase, rather than quote, this disclosure in Kaplan so that he could mislead the examiner and Ethicon could obtain the patent. Opp.Ex. 27 at 2.

Mitek Fact #89: Undisputed.

Mitek Fact #90: Undisputed.

Mitek Fact #91: Undisputed.

Mitek Fact #92: Undisputed.

**Mitek Fact #93:** Disputed. The third Office Action states Kaplan discloses that "the sheath yarn component may be fabricated from one or more non-bioabsorbable fibers." Fact.Ex. 1<sup>2</sup> at 3.

Mitek Fact #94: Undisputed.

**Mitek Fact #95:** Disputed. Defendants do not understand what is meant by the term "biomaterials." However, if what was intended was "bioabsorbable materials," this statement is disputed. Applicants amended claims to specifically include certain non-bioabsorbable materials. Opp.Ex. 27.

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<sup>&</sup>lt;sup>2</sup> "Fact.Ex. 1" refers to the exhibit attached to these Defendants' Responsive Facts.

**Mitek Fact #96:** Disputed. The applicant argued that the invention was patentable over Kaplan only after amending the claim. And in making this contention, applicants intentionally misleading the examiner as explained in the Responses to Mitek Fact #97 and #100.

Mitek Fact #97: Disputed. This statement is misleading since it does not include Mr. Woodrow's misrepresentation of Kaplan by his stating "[i]n one embodiment, the sheath yarn could also contain a non-bioabsorbable yarn of one or more chemical composition." Kaplan actually states "[s]heath yarn component 34 may also be fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being nonbioabsorbable." Mr. Woodrow also stated that Kaplan teaches that the sheath can be made of only absorbable materials and leaves the false impression that a nonabsorbable is added merely to preexisting absorbable components. Mr. Woodrow goes on to misrepresent Kaplan, stating that Kaplan teaches away from a combination of non-absorbable yarns. Opp.Ex. 27; Opp.Ex. 25 at col. 9, ll. 25-28.

Mitek Fact #98: Undisputed.

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Mitek Fact #99: Disputed. Defendants do allege that material information was withheld by applicants with respect to Kaplan. The material information was that Kaplan does disclose a sheath containing all non-bioabsorbable material and that Kaplan teaches away from a combination of all non-absorbable yarns. In his response, Mr. Woodrow cites to the section of the detailed description where Kaplan teaches that the sheath can be made of only nonabsorbable materials. But instead of quoting the relevant sentence, he paraphrases it and argues that the sentence states only that the sheath "could *also* contain a non-absorbable yarn." Opp.Ex. 27 at 2. By doing so, Mr. Woodrow left the false impression that the sentence says that the nonabsorbable component is merely added to preexisting absorbable components. Had he quoted the sentence, as he should have, Mr. Woodrow would not have been able to leave this false

impression. Mr. Woodrow's action becomes all the more suspicious when it is compared to a discussion of Kaplan in a prior response. In that prior response, Ethicon referred to the same sentence in Kaplan. Opp.Ex. 19 6. But this time, when it did not matter (because the issue under consideration had nothing to do with the absorbable/non-absorbable matter), Ethicon quoted the sentence accurately. Id. Yet when it mattered, Mr. Woodrow chose to paraphrase so that he could mislead the examiner and Ethicon could obtain the patent.

Mitek Fact #100: Disputed. This is only one reason why defendants allege that inequitable conduct was committed with respect to Kaplan. Defendants do allege that material information was withheld by applicants with respect to Kaplan. The material information was that Kaplan does disclose a sheath containing all non-bioabsorbable material and that Kaplan teaches away from a combination of all non-absorbable yarns. In his response, Mr. Woodrow cites to the section of the detailed description where Kaplan teaches that the sheath can be made of only non-absorbable materials. But instead of *quoting* the relevant sentence, he paraphrases it and argues that the sentence states only that the sheath "could also contain a non-absorbable yarn." Opp.Ex. 27 at 2. By doing so, Mr. Woodrow left the false impression that the sentence says that the non-absorbable component is merely added to preexisting absorbable components. Had he quoted the sentence, as he should have, Mr. Woodrow would not have been able to leave this false impression. In addition, Mr. Woodrow made these misrepresentations in connection with an amendment made by applicants. Mr. Woodrow did not dispute the assertions made by the examiner in connection with Kaplan, but his misrepresentations were new ones made in connection with the amendment. Mr. Woodrow's action becomes all the more suspicious when it is compared to a discussion of Kaplan in a prior response. In that prior response, Ethicon referred to the same sentence in Kaplan. Opp.Ex. 19 at 6. But this time, when it did not matter (because the issue under consideration had nothing to do with the absorbable/non-absorbable

matter), Ethicon quoted the sentence accurately. Id. Yet when it mattered, Mr. Woodrow chose to paraphrase so that he could mislead the examiner and Ethicon could obtain the patent.

Mitek Fact #101: Disputed. Defendants' allegations of inequitable conduct regarding Burgess are supported by, not based on, Mr. Witherspoon's opinions. Defendants' allegations of inequitable conduct are based on the record. During the prosecution of the '511 application, applicants and their attorney, Matthew S. Goodwin, responded to a rejection based on Burgess by stating that the use of a high tensile polythene thread in a braided construction, with polyester and/or nylon, would have poor qualities for a suture (e.g., poor knot strength, poor knot security, low elongation and poor knot sliding) and that a designer using such materials for a suture would inevitably design an unacceptable suture. Opp.Ex. 2 at 2-4.

Inventor Steckel testified that, at the beginning of the development work that lead to the '446 patent, he and inventor Hunter considered a braided combination of UHMWPE and PET polyester – the same braided combination disclosed in Burgess – and believed that such a combination would have improved knot strength and would make an acceptable suture. These beliefs by the inventors, which were never disclosed to the Patent Office, are diametrically opposite to the position taken by Ethicon when responding to the rejection based on Burgess. It is this record of believing one thing and telling the examiner another, while at the same time withholding from the examiner their actual beliefs, upon which defendants' inequitable conduct allegations with regard to Burgess are based. Opp.Ex. 5 at 189:19-190:5. In addition, Mr. Goodwin testified that Dr. Steckel was his principal contact in preparing and prosecuting the patent application. Opp.Ex. 21 at 75:8-76:7. It is inconceivable that Dr. Steckel's view on such an important issue would be ignored or somehow overlooked. Moreover, prior to filing the response to the Office Action, Mr. Goodwin obtained comments at least from inventor Hunter who, according to Dr. Steckel, was privy to the discussions about the alleged benefits of a braid

made of UHMWPE and polyester. Opp.Ex. 5 at 189:13-24. *See also* Response to Mitek Fact #73.

Mitek Fact #102: Disputed. This statement is incomplete and misleading. The applicants also failed to disclose to the examiner inventor Steckel's actual beliefs with regard to UHMWPE. Inventor Steckel testified that, at the beginning of the development work that lead to the '446 patent, he and inventor Hunter considered a braided combination of UHMWPE and PET polyester – the same braided combination disclosed in Burgess – and believed that such a combination would have improved knot strength and would make an acceptable suture. These beliefs by the inventors, which were never disclosed to the Patent Office, are diametrically opposite to the position taken by Ethicon when responding to the rejection based on Burgess. It is this record of believing one thing and telling the examiner another, while at the same time withholding from the examiner their actual beliefs, upon which defendants' inequitable conduct allegations with regard to Burgess are based. Opp.Ex. 5 at 189:19-190:5.

Mitek Fact #103: Disputed. This statement is incomplete and misleading. The applicants also failed to disclose to the examiner inventor Steckel's actual beliefs with regard to UHMWPE. Inventor Steckel testified that, at the beginning of the development work that lead to the '446 patent, he and inventor Hunter considered a braided combination of UHMWPE and PET polyester – the same braided combination disclosed in Burgess – and believed that such a combination would have improved knot strength and would make an acceptable suture. These beliefs by the inventors, which were never disclosed to the Patent Office, are diametrically opposite to the position taken by Ethicon when responding to the rejection based on Burgess. It is this record of believing one thing and telling the examiner another, while at the same time withholding from the examiner their actual beliefs, upon which defendants' inequitable conduct allegations with regard to Burgess are based. Opp.Ex. 5 at 189:19-190:5.

Mitek Fact #104: Undisputed.

Mitek Fact #105: Undisputed.

Mitek Fact #106: Undisputed.

Mitek Fact #107: Undisputed.

Mitek Fact #108: Disputed. Kaplan *twice* teaches that the sheath may, in some circumstances, only include non-absorbable material. In the summary of the invention, Kaplan explains that the sheath yarn can be formed from the same material as the core yarn. The core yarn is described as non-bioabsorbable. Obviously, if the sheath is made of the same material, it also can be all non-bioabsorbable. Opp.Ex. 25 at col. 2, ll. 55-56, 59-61. Second, in the detailed discussion of the invention, Kaplan states that the '[s]heath yarn component may also be fabricated from individual filaments having more that two different chemical compositions, *one or more* of which optionally being nonbioabsorbable." Opp.Ex. 25 at col. 9, ll. 25-28. [Emphasis added]. A disclosure that "one or more" of the components can be non-absorbable must include, as a disclosed possibility, that all of the components are non-absorbable.

Mr.Woodrow, who submitted the false statements, must have read the summary of the invention because he pointed to the summary to support his position. Opp.Ex. 26 at 159:15-20. Having done so, he must have known that Kaplan discloses a sheath made of only non-absorbable materials and that his assertion to the contrary is not accurate.

Second, in his response, Mr. Woodrow cites to the section of the detailed description where Kaplan teaches that the sheath can be made of only non-absorbable materials. Opp.Ex. 27 at 2 [citing to Kaplan at col. 9, Il. 25-27]. But instead of *quoting* the relevant sentence, he paraphrases it and argues that the sentence states only that the sheath "could *also* contain a non-absorbable yarn." Opp.Ex. 27 at 2. By doing so, Mr. Woodrow left the false impression that the sentence says that the non-absorbable component is merely added to preexisting absorbable

components. Had he quoted the sentence, as he should have, Mr. Woodrow would not have been able to leave this false impression. Mr. Woodrow's action becomes all the more suspicious when it is compared to a discussion of Kaplan in a prior response. In that prior response, Ethicon referred to the same sentence in Kaplan. Opp.Ex. 19 at 6. But this time, when it did not matter (because the issue under consideration had nothing to do with the absorbable/non-absorbable matter), Ethicon quoted the sentence accurately. Id. Yet when it mattered, Mr. Woodrow chose to paraphrase so that he could mislead the examiner and Ethicon could obtain the patent.

Mitek Fact #109: Undisputed.

Mitek Fact #110: Undisputed.

Mitek Fact #111: Disputed. The Answers identified the misstatements and alleged that intent was present because they could not have truthfully made these statements to the Patent Office if they believed that UHMWPE fell within their claimed invention and because they knew that the Patent Office would rely on the statements in reconsidering the rejections based on Burgess. Opp.Ex. 23 at 4; Opp.Ex. 24 at 4.

Disputed. In addition, defendants alleged intent to deceive in their Mitek Fact #112: answers to DePuy Mitek's complaint. See Response to Mitek Fact # 111. Intent is inferred from the facts and circumstances surrounding the applicant's overall conduct. Kaplan twice teaches that the sheath may, in some circumstances, only include non-absorbable material. In the summary of the invention, Kaplan explains that the sheath yarn can be formed from the same material as the core yarn. The core yarn is described as non-bioabsorbable. Obviously, if the sheath is made of the same material, it also can be all non-bioabsorbable. Opp.Ex. 5 at col. 2, ll. 55-56, 59-61. Second, in the detailed discussion of the invention, Kaplan states that the"[s]heath yarn component may also be fabricated from individual filaments having more that two different chemical compositions, one or more of which optionally being nonbioabsorbable." Opp.Ex. 5 at

col. 9, ll. 25-28. [Emphasis added]. A disclosure that "one or more" of the components can be non-absorbable must include, as a disclosed possibility, that all of the components are non-absorbable.

Mr.Woodrow, who submitted the false statements, must have read the summary of the invention because he pointed to the summary to support his position. Opp.Ex. 26 at 159:15-20. Having done so, he must have known that Kaplan discloses a sheath made of only non-absorbable materials and that his assertion to the contrary is not accurate.

Second, in his response, Mr. Woodrow cites to the section of the detailed description where Kaplan teaches that the sheath can be made of only non-absorbable materials. Opp.Ex. 27 at 2 [citing to Kaplan at col. 9, ll. 25-27]. But instead of *quoting* the relevant sentence, he paraphrases it and argues that the sentence states only that the sheath "could *also* contain a non-absorbable yarn." Opp.Ex. 27 at 2. By doing so, Mr. Woodrow left the false impression that the sentence says that the non-absorbable component is merely added to preexisting absorbable components. Had he quoted the sentence, as he should have, Mr. Woodrow would not have been able to leave this false impression. Mr. Woodrow's action becomes all the more suspicious when it is compared to a discussion of Kaplan in a prior response. In that prior response, Ethicon referred to the same sentence in Kaplan. Opp.Ex. 19 at 6. But this time, when it did not matter (because the issue under consideration had nothing to do with the absorbable/non-absorbable matter), Ethicon *quoted* the sentence accurately. *Id.* Yet when it mattered, Mr. Woodrow chose to paraphrase so that he could mislead the examiner and Ethicon could obtain the patent.

Mitek Fact #113: Disputed. This statement is misleading. Defendants' expert, Mr. Witherspoon, included in his reports, as support for his opinion, facts learned at the deposition of Dr. Steckel. Opp.Ex. 18 at ¶¶ 5-8. See also Response to Mitek Fact #101 and #112.

Mitek Fact #114: Disputed. Kaplan *twice* teaches that the sheath may, in some circumstances, only include non-absorbable material. In the summary of the invention, Kaplan explains that the sheath yarn can be formed from the same material as the core yarn. The core yarn is described as non-bioabsorbable. Obviously, if the sheath is made of the same material, it also can be all non-bioabsorbable. Opp.Ex. 5 at col. 2, ll. 55-56, 59-61. Second, in the detailed discussion of the invention, Kaplan states that the"[s]heath yarn component may also be fabricated from individual filaments having more that two different chemical compositions, one or more of which optionally being nonbioabsorbable." Opp.Ex. 5 at col. 9, ll. 25-28.] [Emphasis added]. A disclosure that "one or more" of the components can be non-absorbable must include, as a disclosed possibility, that all of the components are non-absorbable.

Mr. Woodrow, who submitted the false statements, must have read the summary of the invention because he pointed to the summary to support his position. Opp.Ex. 26 at 159:15-20. Having done so, he must have known that Kaplan discloses a sheath made of only nonabsorbable materials and that his assertion to the contrary is not accurate.

Second, in his response, Mr. Woodrow cites to the section of the detailed description where Kaplan teaches that the sheath can be made of only non-absorbable materials. Opp.Ex. 27 at 2 [citing to Kaplan at col. 9, 11. 25-27]. But instead of quoting the relevant sentence, he paraphrases it and argues that the sentence states only that the sheath "could also contain a nonabsorbable yarn." Opp.Ex. 27 at 2. By doing so, Mr. Woodrow left the false impression that the sentence says that the non-absorbable component is merely added to preexisting absorbable components. Had he quoted the sentence, as he should have, Mr. Woodrow would not have been able to leave this false impression. Mr. Woodrow's action becomes all the more suspicious when it is compared to a discussion of Kaplan in a prior response. In that prior response, Ethicon referred to the same sentence in Kaplan. Opp.Ex. 19 at 6. But this time, when it did not matter

(because the issue under consideration had nothing to do with the absorbable/non-absorbable matter), Ethicon *quoted* the sentence accurately. *Id*. Yet when it mattered, Mr. Woodrow chose to paraphrase so that he could mislead the examiner and Ethicon could obtain the patent.

Mitek Fact #115: Disputed. This statement is misleading. During his deposition, Dr. Steckel was referring to a braid of the same materials as the braid discussed in the response to the Burgess rejection – a braid of UHMPWE and PET. This is the same braided material that applicants told the examiner would have poor knot strength and security an would make an unacceptable suture. Opp.Ex. 18 at ¶¶ 5-8. See also Response to Mitek Facts #73 and 101.

Mitek Fact #116: Undisputed.

Mitek Fact #117: Undisputed.

Mitek Fact #118: Disputed. This statement is misleading since this is not the basis of defendants' inequitable conduct allegations.

Mitek Fact #119: Undisputed.

Mitek Fact #120: Disputed. Mr. Witherspoon, in his reports and at his deposition, expressed no doubt that the representations were material. Opp.Ex. 16 at ¶ 63; Opp.Ex. 20 at 138:25-140:21. Mr. Witherspoon explained that he used the phrase "may have been a violation" because he had not seen direct evidence of a knowledge train from Dr. Steckel to Mr. Goodwin. Opp.Ex. 20 at 185:13-186:20. But Mr. Witherspoon went on to explain that there was circumstantial evidence that Dr. Steckel knew what the patent examiner was told and that there was evidence to infer what they knew. Ex. 20 at 186:6-8, 18-20. See also Response to Mitek Fact # 101.

Mitek Fact #121: Disputed. The Answers identified the misstatements and alleged that intent was present because they could not have truthfully made these statements to the Patent Office if they believed that UHMWPE fell within their claimed invention and because they knew

that the Patent Office would rely on the statements in reconsidering the rejections based on Burgess. Opp.Ex. 23 at 4; Opp.Ex. 24 at 4. The interrogatory responses contain similar allegations of intent. Opp.Ex. 14 at 18-20; Opp.Ex. 15 at 18-20.

Mitek Fact #122: Disputed. The Answers identified the misstatements and alleged that intent was present because they could not have truthfully made these statements to the Patent Office if they believed that UHMWPE fell within their claimed invention and because they knew that the Patent Office would rely on the statements in reconsidering the rejections based on Burgess. Opp.Ex. 23 at 4; Opp.Ex. 24 at 4. The interrogatory responses contain similar allegations of intent. Opp.Ex. 14 at 18-20; Opp.Ex. 15 at 18-20. See also Response to Mitek Fact # 101.

Mitek Fact #123: Disputed. This statement is misleading. Defendants' expert, Mr. Witherspoon, included in his reports, as support for his opinion, facts learned at the deposition of Dr. Steckel. Opp.Ex. 18 at ¶¶ 5-8. See also Response to Mitek Fact # 101 and #112.

Mitek Fact#124: Undisputed.

Mitek Fact #125: Undisputed, to the extent that PE, as used in the '446 patent, means general purpose PE. Otherwise, disputed. See Response to Mitek Facts # 7 and 12.

Mitek Fact #126: Disputed. There is no written evidence to support this statement and DePuy Mitek points to none. The written evidence that does exist, including Dr. Steckel's notebook and the '446 patent (Opp.Ex. 11) refute this fact. For example, the '446 patent describes "PE" as weak and pliable and UHMWPE is strong and stiff. Opp.Ex. 9 at ¶ 56.

Mitek Fact 127: Undisputed.

Dated: September 1, 2006 Respectfully submitted,

By: /s/Charles W. Saber
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Counsel for Defendants Arthrex, Inc. and Pearsalls Ltd.

### **CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing Defendants' Responses to DePuy Mitek's Statement of Undisputed Material Facts in Support of its Motion for Summary Judgment of Infringement and No Inequitable Conduct was served, via the Court's email notification system on the following counsel for Plaintiff on the 1st day of September 2006:

Lynn A. Malinoski Woodcock Washburn, LLP One Liberty Place, 46th Floor Philadelphia, PA. 19103 Telephone: (215) 568-3100 Facsimile: (215) 568-3439

Daniel J. Gleason Nutter McClennan & Fish LLP World Trade Center West 155 Seaport Boulevard Boston, MA 02210-2604 Telephone: (617) 439-2000

Facsimile: (617) 310-9000

/s/Charles	W. Saber	

# FACT EXHIBIT 1

### Case 1:04-cv-12457-PBS



### Filed 09/01/2006

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### UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

FIRST NAMED INVENTOR ATTORNEY DOCKET NO. SERIAL NUMBER FILING DATE ETH-782 HUNTER 02/19/92 07/838.511 EXAMINER RAIMUND. 15N1 ROBERT L. MINIER ONE JOHNSON & JOHNSON PLAZA PAPER NUMBER ART UNIT NEW BRUNSWICK, NJ 08933-7003 1504 03/18/93 DATE MAILED: This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS Responsive to communication filed on Dec. 2, 1992 
This action is made final. This application has been examined 3 \_ month(s), \_\_\_\_\_ days from the date of this letter. A shortened statutory period for response to this action is set to expire...... Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133 THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION: Notice of References Cited by Examiner, PTO-892. 2. Notice re Patent Drawing, PTO-948. 4. Notice of Informal Patent Application, Form PTO-152. ☐ Notice of Art Cited by Applicant, PTO-1449. 6. 🗆 ☐ Information on How to Effect Drawing Changes, PTO-1474. SUMMARY OF ACTION Part II 1 - 24 are pending in the application. \_\_ are withdrawn from consideration. Of the above, claims have been cancelled. 2. Claims\_ ☐ Cialma are allowed. 21 - 24 T Claims \_ are objected to. 5. Claims \_\_\_\_ are subject to restriction or election requirement. 8. Claims \_\_ 7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 8. Formal drawings are required in response to this Office action. \_ . Under 37 C.F.R. 1.84 these drawings 9. The corrected or substitute drawings have been received on \_\_\_\_ are acceptable. not acceptable (see explanation or Notice re Patent Drawing, PTO-948). 10. The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_\_ has (have) been approved by the examiner. disapproved by the examiner (see explanation). \_\_\_\_\_, has been approved. disapproved (see explanation). 11. The proposed drawing correction, filed on \_\_\_\_ 12. Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has Deen received not been received : filed on . been filed in parent application, serial no. \_\_\_\_ 13. 

Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayte, 1935 C.D. 11; 453 O.G. 213. 14. Other

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 21 is rejected under 35 U.S.C. § 102(e) as being anticipated by Kaplan et al.

Kaplan et al. discloses a connective tissue prosthesis comprising a braided sheath yarn component and a core yarn The braided sheath comprises braided filaments or component. braided filament bundles (column 9, lines 4-12). A sheath component containing filaments of different chemical compositions is specifically disclosed (column 9, lines 12-16). Claim 21 is therefore anticipated by Kaplan et al.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as

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prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 21-24 are rejected under 35 U.S.C. § 103 as being unpatentable over Doddi et al. taken with Kaplan et al.

Doddi et al. disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, Suitable biocompatible, non absorbable filaments lines 47-56). include PET and PTFE (column 9, lines 51-53).

Kaplan et al. discloses a ligament prosthesis comprising a core component and a braided sheath component. The core component is "made up of one or more biocompatible, essentially nonbioabsorbable..." filaments (column 9, lines 1-3). The sheath yarn component may be fabricated from one or more non-bioabsorbable fibers (column 9, lines 25-28). It would have been obvious to form the sheath component of the device of Kaplan et al. from PTFE and PET. PTFE is known to inpart improved knot run down properties to sutures (see Block U.S. Pat. No. 3,527,650). PET is noted for its low cost and high strength. The core yarn component must be non-Since PET is nonbioabsorbable (column 4, lines 45-46). bioabsorbable, biocompatible and has the desirable properties noted above, its use as the core component would have been obvious. Claims 21 and 22 are therefore unpatentable over Doddi et al. taken

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with Kaplan et al.

Kaplan et al. fail to disclose the prosthesis of their invention connected to a needle. Prosthesis are, however, implanted in the body using a needle. Claims 23 and 24 are therefore unpatentable over Doddi et al. taken with Kaplan et al.

Applicant's arguments with respect to claims 21-24 have been considered but are deemed to be moot in view of the new grounds of rejection.

Any inquiry concerning this communication should be directed to Chris Raimund at telephone number (703) 308-2374.

C. Raimund:pdw

February 25, 1993

GEORGE F. LESMES

SUPERVISORY PATENT EXAMINER

**GROUP 150** 

# FACT EXHIBIT 2

### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, Civil Action No. 04-12457 PBS v. Arthrex, Inc. a Delaware Corporation Defendant.

### EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE CONCERNING INVALIDITY OF U.S. PATENT NO. 5,314,446

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his expert report as follows.

- Invalidity based on 35 U.S.C. § 103 in view of the Burgess 2. application and other prior art
  - The Burgess application combined with the Cohan article a.

The Burgess application describes a heterogeneous braid of UHMWPE and polyester and/or nylon for use as a fishing line. Thus, the Burgess application discloses every limitation of claim 1 of the '446 patent (if the Court interprets PE to include UHMWPE), except that Burgess is not a sterilized suture. As previously mentioned, the Burgess application was cited by the examiner in a rejection of claims 21-24 of the '511 application. In rejecting the claims, the examiner noted that the Burgess application disclosed a heterogeneous braided fishing line made up of two dissimilar polymers together to form a combined structure which embodies the desirable properties of each fiber. Ex. 4 at 4. The examiner reasoned that it would have been obvious to a person of ordinary skill in the art at the time to use a heterogeneous braid with these properties for a suture since: i) braided sutures were, at the time, well known in the art; ii) many of the requirements of sutures were comparable to those of fishing line - strength, low stretchability, etc.; and iii) many of the same materials were used to make both fishing lines and sutures. Ex. 4 at 5.

I agree with the examiner's reasoning that the Burgess application makes it known to braid two dissimilar fibers together to achieve the desired properties of each fiber, as well as the examiner's reasoning as to why it would have been obvious to a

person of ordinary skill in the art, in February 1992, to use a heterogeneous braid, such as that disclosed in the Burgess application, for a suture. In addition, in my opinion, one looking to find a manufacturer of a braided suture would seek out fishing line manufacturers as a potential braiding processor.

In response to the rejection, Ethicon's attorney did not dispute the examiner's finding that the Burgess application suggests the combination of two dissimilar fibers to achieve the desired properties of each. Rather, Ethicon stated that if one were to make a product with high tensile polythene (which in the Burgess application was UHMWPE), it would be "unsuitable for use as sutures" because UHMWPE has "low elongation" and because UHMWPE has "poor knot strength properties," including "poor knot strength and security." Ex. 6 at 2-3.

The Cohan article (published in 1985), however, teaches a person of ordinary skill in the art that Ethicon's attorney was incorrect on all counts. In fact, not only did Cohan teach a suitable suture, but he also taught that by using UHMWPE, one can build a superior suture. More specifically, the Cohan article explains that a superior suture can be made even though UHMWPE has low elongation and that the suture made of UHMPWPE had, among other things, *superior* knot strength (Ex. 8 at Table 2) and knot security, as compared with other more traditional suture materials at the time (e.g., nylon, polypropylene and polyester). Ex. 8 at 1. Thus, the Cohan article plainly suggests that UHMWPE has properties that can be used for a suture.